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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,031	10/16/2001	Mirna Rapp	0843.0002	7920

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EXAMINER	
SCHNIZER, HOLLY G	
ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,031	RAPP, MIRNA	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-65 and 67-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25-58,61-65,68,69 and 71-73* is/are allowed.

6)☒ Claim(s) *59,67 and 70* is/are rejected.

7)☒ Claim(s) *60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/30/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/04 has been entered.

Status of the Claims

Claims 25-65 and 67-73 are currently pending and have been considered in this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 59 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Luck et al. (DE 44 41 167; ref. cited in IDS filed 3/30/05-- translation provided by the Office is attached hereto).

Luck et al. teach a method of drying plasma (which contains a mixture of thrombin, fibrinogen, and factor XIII) in flowable solid granules, which comprises providing a solution of plasma, drying the plasma solution in a fluidized bed apparatus, and forming the flowable solid granules. The granules produced by the method of Luck et al. are 100-200 μm (see translation, p. 3, last lines of 2nd paragraph), which is within the range of 50-1000 μm. Luck et al. also teach the formulation made by the process (plasma (which contains a mixture of thrombin, fibrinogen, and factor XIII) in flowable solid granules that are 100-200 μm). The examiner notes that "fibrin tissue adhesive" is considered an intended use of the formulation presently claimed and the formulation made by the method presently claimed. The present claims do not contain closed language as to the contents of the claimed formulation and are therefore not considered limited to only thrombin, fibrinogen, and factor XIII. Thrombin, fibrinogen, and factor XIII are all proteins contained in plasma and thus the formulation of Luck et al. contains all the components of the presently claimed formulation. The method of Luck et al. contains all of the method steps as that presently claimed and produces a formulation that contains all the components of the formulation made by the presently claimed method. Thus, Luck et al. meets the limitations of the claims.

Claims 59 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Luck et al. (US 2003/0143518; ref. cited in IDS filed 3/30/05).

Luck et al. teach a method of drying plasma (which contains a mixture of thrombin, fibrinogen, and factor XIII) in flowable solid granules, which comprises providing a solution of plasma, drying the plasma solution in a fluidized bed apparatus, and forming the flowable solid granules. The granules produced by the method of Luck et al. are 100-200 μm (p. 2, [0012,]), which is within the range of 50-1000 μm presently claimed. Luck et al. also teach the formulation made by the process (plasma (which contains a mixture of thrombin, fibrinogen, and factor XIII) in flowable solid granules that are 100-200 μm) (pp. 1-3). The examiner notes that "fibrin tissue adhesive" is considered an intended use of the formulation presently claimed and the formulation made by the method presently claimed. The present claims do not contain closed language as to the contents of the claimed formulation and are therefore not considered limited to only thrombin, fibrinogen, and factor XIII. Thrombin, fibrinogen, and factor XIII are all proteins contained in plasma and thus the formulation of Luck et al. contains all the components of the presently claimed formulation. The method of Luck et al. contains all of the method steps as that presently claimed and produces a formulation that contains all the components of the formulation made by the presently claimed method. Thus, Luck et al. meets the limitations of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 depends from cancelled claim 66 and therefore is unclear as to the metes and bounds of the claim.

Claim Objections

Claim 60 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to include every limitation of the claim from which it depends. Claim 60 is dependent from Claim 59, which is drawn to a product that contains a mixture of thrombin, fibrinogen, and factor XIII. However, Claim 60 recites that the mixture "consists of separately dried thrombin and fibrinogen granules". Therefore, due to the closed language "consists of", it appears that the mixture of Claim 60 does not contain factor XIII as is required in the mixture of Claim 59 from which it depends. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Conclusions

The examiner notes that US Patent No. 4,427,651 (cited in IDS filed 6/22/01) teaches that to ensure good sprayability of a fibrin adhesive, the desired average particle size is preferably between 0.1 μm and 5 μm. The '651 patent teaches that finer powders have a risk of agglomeration and clogging and coarser powders cannot be sufficiently sprayed and their dissolution in the body fluid is delayed (Col. 7, lines 44-50). A thorough search of the prior art did not reveal any teaching or suggestion of the benefit of fibrin adhesives with particle sizes in the presently claimed ranges. Therefore, even though Luck et al. teaches that the method disclosed therein can be used for plasma products such a fibrinogen, thrombin, factor XIII, and albumin (see p. 1, [0011] of the '518 publication for example), it appears that one of ordinary skill in the art at the time of the invention would not have used the method of Luck et al. for drying fibrin adhesive formulations in particular since it would have resulted in particle sizes that would not be sufficiently sprayed and would have delayed dissolution in the body as taught in the '651 patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
June 25, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER

JASEMINE C. CHAMBERS
DIRECTOR
TECHNOLOGY CENTER 1600